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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/661,156	09/11/2003	Aaron K. Sato	D0617.70012US00	6772

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EXAMINER	
DESAI, ANAND U	

ART UNIT	PAPER NUMBER
1656	

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03/31/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/661,156	SATO ET AL.	
	Examiner	Art Unit	
	ANAND U. DESAI	1656	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-27,32,53,54,76,78,158,175,195,198 and 199* is/are pending in the application.

4a) Of the above claim(s) *1-9,11,12,27,32,53,54,76,158,175 and 195* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *10, 13-26, 78, 198, and 199* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 30, 2008 has been entered.

2. Claims 1-9, 11, 12, 27, 32, 53, 54, 76, 158, 175, and 195 have been withdrawn previously. Claims 10, 13-26, 78, 198, and 199 are currently under examination.

Withdrawal of Rejections

3. The rejection of claims 10, 13, 15-26, and 78 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement is withdrawn based on the 25 sequences that fall within the scope of the consensus sequences recited in independent claims 10 and 78 (see 1/30/2008 Remarks, page 43, last paragraph).

Pending Rejections

Double Patenting

4. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re*

Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

5. Claims 78, 198 and 199 stand rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim1, 11-20 of U.S. Patent No. 7,211,240 (Previously cited as US 2004/0018974 A1, SN 10/379,287 in office action mailed November 9, 2006). Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the copending application are drawn to a compound comprising a polypeptide sequence that is encompassed by claims 78, 198, and 199, and can bind to the same tyrosine kinase receptor, KDR, and the ligand-receptor complex, KDR/VEGF. SEQ ID NO: 18 of the issued U.S. Patent has 100% identity with SEQ ID NO: 308 of the instant application. The SEQ ID NO:'s are considered to be an obvious variant of each other, since Applicant state SEQ ID NO: 310 is a designated subset of the sequences for searching purposes (see Response to Restriction dated 9/18/2006, 2nd indented paragraph on page 2).

Response to Remarks

6. Applicants' state that it may remove the rejection with a terminal disclaimer when the claims are otherwise indicated as allowable.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 10, 13-26, and 78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

9. Claims 10 and 78 describe the variables Z_1 and Z_2 as a polypeptide. It is unclear how one amino acid can be a polypeptide?

10. Claim 78 also describes a polypeptide at the termini of at least one amino acid. It is unclear how a polypeptide is one amino acid?

11. Claim 13 describes a peptide as being one amino acid. It is unclear how a peptide is one amino acid?

12. Dependent claims are rejected for failing to cure the indefiniteness of the rejected claims.

Claim Rejections - 35 USC § 112, First Paragraph, Written Description

13. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

14. Claims 14 stands rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant

art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was explained in the office action mailed November 9, 2006.

Response to Remarks

15. Applicant's state they show possession of the claimed invention by describing the claimed invention with all of its limitations. Applicant's state they identify the written support in the specification for each element recited in the claimed inventions. Particularly for claim 14, the applicants recite support on page 26, lines 22-26, which states the modifications contemplated. Applicants further state that SEQ ID NOs: 137, 138, 140-142, 146, 147, 149, 156, 162, 164, 169-171, 175, 185, 304-308, 331, 343, 344, and 353 fall within the scope of the consensus sequences recited in independent claims 10 and 78. Applicants state that the 25 peptides each having variations as encompassed by the claims is a representative number of species to demonstrate possession of the genus.

16. Applicant's arguments filed January 30, 2008 have been fully considered but they are not persuasive. The disclosed peptides are not representative of the modifications recited in claim 14. For example, there is no species from the polypeptides recited that comprise a polypeptide with a D-amino acid, glycosylated amino acid, and a disulfide bonded polypeptide. The disclosure does not describe what regions of the polypeptide can be modified with the envisioned modifications of claim 14. There is no correlation of the structural modifications with function. The claim does little more than define the invention by function, which is insufficient to satisfy written description requirement.

Claim Rejections - 35 USC § 102

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 78 and 198 are rejected under 35 U.S.C. 102(b) as being anticipated by Schatz (U.S. Patent 5,723,584).

Schatz describes a peptide sequence that comprises the sequence Ala-Gln-Lys-Val-Glu (see claim 3, SEQ ID NO: 71, col. 67, lines 37 and 38). The peptide encompasses the sequence disclosed in claims 78. For claim 198, the phrase "comprising an amino acid sequence of" is interpreted to encompass any sequence within the SEQ ID NOs. Therefore, the sequence Ala-Gln is an amino acid sequence of SEQ ID NO: 304. It is recognized that the structure of a peptide sequence confers function, and therefore since the peptide meets the structural limitations it must necessarily and inherently have the function being claimed.

Claim Rejections - 35 USC § 102 /Claim Rejections - 35 USC § 103

19. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

20. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

21. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

22. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

23. Claims 10 and 13-17 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Schatz (U.S. Patent 5,723,584).

Schatz describes a peptide sequence that comprises the sequence Ala-Gln-Lys-Val-Glu (see claim 3, SEQ ID NO: 71, col. 67, lines 37 and 38). The peptide encompasses the sequence disclosed in claims 10. Schatz describes the peptide as being biotinylated by a biotin ligase (see claim 2). Biotin is added to proteins in vivo through the formation of an amide bond between the biotin carboxyl group and the epsilon-amino group of specific lysine residues (see col. 2, line 66

through col. 3, line 2). Biotin labeling of molecules not normally biotinylated can be used to label, detect, purify, and/or immobilize molecules (see col. 2, lines 51-53). Schatz discloses the use of ^{3}H-biotin for labeling, while not explicitly labeling the particular peptide, it would have been obvious to the person having ordinary skill in the art to label the peptide identified as SEQ ID NO: 71, because the disclosure describes the manner of using ^{3}H-biotin to label peptides (see col. 16, line 59 through col. 17, line 4).

Therefore, it would have been obvious to the person having ordinary skill in the art to label the peptide identified as SEQ ID NO: 71, because the process of using ^{3}H-biotin to label peptides was known in the art.

24. Claims 18-22 and 26 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatz (U.S. Patent 5,723,584) as applied to claims 10 and 13-17 above, and further in view of Reubi (U.S. Patent 6,312,661 B1).

Schatz discloses the labeling of peptides comprising the consensus sequence Ala-Gln-Lys-Val-Glu (see 102(b)/103(a) rejection above). Schatz does not explicitly disclose the use of the selected radionuclide's, paramagnetic metal ions, or chelators. Reubi discloses the use of radioactive halogen atoms being attached to a Try residue on peptide sequence or by labeling with a paramagnetic metal ion by means of a chelating group (see col. 4, line 48 through col. 7, line 52). SEQ ID NO: 71 disclosed by Schatz does comprise a Tyr residue (see SEQ ID NO: 71).

It would have been obvious to the person having ordinary skill in the art to use known techniques for labeling peptides, because the art has described the use of the selected

radionuclide's, paramagnetic metal ions and chelators to label polypeptides. It is that the product is not one of innovation, but of ordinary skill and common sense using known techniques with anticipated success.

25. Claims 23-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schatz (U.S. Patent 5,723,584) as applied to claims 10 and 13-17 above, and further in view of Wescott et al. (U.S. Patent 6,984,373 B2; previously cited).

Schatz discloses the labeling of peptides comprising the consensus sequence Ala-Gln-Lys-Val-Glu (see 102(b)/103(a) rejection above). Schatz does not explicitly disclose the use of the ultrasound contrast agent label with a fluorinated gas. Wescott et al. discloses the labeling of peptides with a fluorinated gas (see col. 23, lines 18-30).

It would have been obvious to the person having ordinary skill in the art to use known techniques for labeling peptides, because the art has described the use of fluorinated gas as an ultrasound contrast agent with a labeled peptides. It is that the product is not one of innovation, but of ordinary skill and common sense using known techniques with anticipated success.

Conclusion

26. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ANAND U. DESAI whose telephone number is (571)272-0947. The examiner can normally be reached on Monday - Friday 9:00 a.m. - 5:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Kathleen Kerr Bragdon can be reached on (517) 272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

March 27, 2008

/Anand U Desai, Ph.D./
Patent Examiner, Art Unit 1656